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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/066,964 | 02/04/2002 | Keith Biggadike | PG4709 | 6058 |

7590

10/03/2003

Glaxo Wellcome Inc.
5 Moore Drive, Mai B497
Durham, NC 27709

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| EXAMINER |
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BADIO, BARBARA P

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,964

Applicant(s)

BIGGADIKE, KEITH

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The provisional rejection of claims 1-19 under 35 USC 101 over claims 18, 22 and 23 of copending Application No. 09/958,050 is withdrawn.
3. The provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 13-17, 20, 21 and 24-26 of copending Application No. 09/958,050 is withdrawn.
4. The rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-7 and 10-18 of U.S. Patent No. 6,537,983.
5. The provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-14 of copending Application No. 10/066,951 is withdrawn.

6. The provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-7 and 10-18 of copending Application No. 10/066,836 is maintained.

The rejection is maintained because both the instant invention and copending Application No. 10/066,836 encompass compositions comprising (a) the 17 α -(2-furanylcabanoyloxy) ester of fluticasone, (b) a liquefied hydrofluoroalkane gas and (c) a long-acting β_2 -adrenoreceptor agonist. The instant claims, unlike the latter claims, recite an aerosol formulation comprising the claimed compound and liquefied hydrofluoroalkane gas. However, like the instant invention, the composition of copending Application No. 10/066,836 includes aerosol formulations for administration by inhalation comprising hydrofluoroalkane such as 1,1,1,2-tetrafluoroethane (see for example, section 0029 of the latter application). It is also noted that like the latter application, the instant claims encompass compositions comprising a long-acting β_2 -adrenoreceptor agonist (see for example, page 12, lines 6-28 of the present application). Thus, the claimed composition of present application encompasses the composition of copending Application No. 10/066,836.

For these reasons and those given in Paper No.7, the provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-7 and 10-18 of copending Application No. 10/066,836 is maintained.

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7. The provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of copending Application No. 10/067,020 is maintained.

The rejection is maintained because both the instant invention and copending Application No. 10/067,020 encompass aerosol formulations comprising an aqueous suspension of the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The aqueous suspension of the latter application can be administration by inhalation (see for example, section 0040). The utilization of aerosol formulation for delivery by inhalation of an active agent is prima facie obvious (see definition of an aerosol in Stedman's Medical Dictionary 27th Edition and see #6 above). Thus, the claimed composition of the present application encompasses the composition of copending Application No. 10/067,020.

For this reason and those given in Paper No. 7, the provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of copending Application No. 10/067,020 is maintained.

8. The provisional rejections of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over (a) claims 1-8, 10 and 11 of copending Application No. 10/200,364 and (b) claims 1-15 of copending Application No. 10/241,658 are maintained.

The rejections are maintained because the instant invention encompasses crystalline forms of the claimed compound as recited by copending Application Nos.

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10/200,364 and 10/241,658(see for example, page 14, line 21 – page 15, line 31 of the present application). Both copending Application Nos. 10/200,364 and 10/241,658 also encompass aerosol formulations comprising 17 α -(2-furanylcabanoyloxy) ester of fluticasone. Thus, the claimed aerosol composition of the present application encompasses the composition of copending Application Nos. 10/200,364 and 10/241,658.

For this reason and those given in Paper No. 7, the provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-8, 10 and 11 of copending Application No. 10/200,364 is maintained.

9. The provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-24, 26 and 27 of copending Application No. 10/067,010 is withdrawn.

10. The provisional rejection of claims 1-19 under the judicially created doctrine of obviousness-type double patenting over claims 1-6 and 8-14 of copending Application No. 10/281,735 is withdrawn.

Other Matters

11. The examiner notes Applicant's statement that the examiner agreed to withdraw the "obviousness-type" double patenting rejection based on '020, '010, '364, '658, '836 and '735 application during an interview. However, the examiner is not in the habit of

agreeing to applicant's argument during an interview without first reviewing the rejection(s) in light of applicant's argument(s) presented. Thus, the examiner apologizes for any misunderstanding of what the examiner's action would be after the discussion of the above-mentioned applications as they relate to the presently claimed invention.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

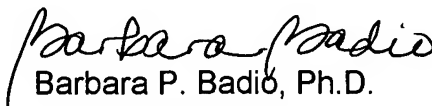
Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
September 30, 2003